

Remarks

This amendment responds to the Office Action mailed September 9, 2005 (Paper No. 20050831). Claims 1-42 are pending.

Interview Summary

The courtesy extended in the personal interview of February 27, 2006 to the lead inventor, Mr. William Carroll, and his representative Evan Smith by the Examiners responsible for this case is noted with appreciation. In the interview, the applicant and his representative briefly explained the operation of the invention described in the specification and discussed features of the references relied upon in the pending rejections. The information provided to the Examiners is summarized in the remarks that follow. The Examiners indicated that they would conduct a further search in light of the information provided.

Remarks on Amendments

In this amendment, the independent claims are amended to increase their clarity and to broaden their scope, and not for reasons of patentability. In particular, the independent apparatus claims are amended to recite that the electrodes are “adapted to be” located “proximate to” the spinal cord or dorsal column, as applicable, while the method claims are amended to recite that the electrodes are located “proximate to” the spinal cord or dorsal column, as applicable. Thus, as amended, the claims have been broadened so that the electrodes need not actually be placed on the spinal cord or dorsal column to create an infringement. The amendments also respond to a request by the Examiner in the recent

interview that applicants amend the claims to make it clear that applicant is not claiming the spinal cord and/or dorsal column as an element of the invention in the apparatus claims.

Response to Prior Art Rejections

The pending rejections are respectfully traversed, and reconsideration is requested based on the remarks and amendments herein.

Claims 1 and 15 were rejected under 35 U.S.C. 102 based on U.S. Patent 5,107,835 to Thomas. Claims 1 and 15 recite an interferential current generator using common sine wave generators, and at least two pairs of implantable electrodes connected to the generator and adapted to be located on a subject's spinal cord (claim 1) or dorsal column (claim 15), wherein each of the two pairs of implantable electrodes produces a separate electrical circuit carrying an alternating current of a different frequency. The recited features make it possible to apply an interferential current to the spinal cord (claim 1) or dorsal column (claim 15) for the treatment of intractable pain syndromes. Applicants do not believe the prior art discloses or suggests the application of implantable electrodes to the spinal cord or dorsal column for intractable pain management.

Instead, the cited Thomas patent discloses a treatment device with a single sine wave generator and a pulse generator. The device generates a periodic-exponential signal that is inductively coupled to four electrodes. Two electrodes provide a common connection to one side of the inductor. The other two electrodes are connected to the other side of the inductor and have individual rheostats for adjusting their output. Thus, among other distinctions, Thomas produces the same frequency output through each electrode pair. Thomas thus does not disclose or suggest an interferential signal, nor does Thomas disclose two pairs of

implantable electrodes that produce a separate circuit carrying an alternating current of different frequency. Thomas specifically teaches away from the idea of using sinusoidal signals (see col. 1 line 62 to col. 2 line 7). There is no disclosure of interferential signals, and no disclosure of applying such signals to the spinal cord and/or dorsal column for relieving intractable pain. All of the rejections that rely on Thomas to show the basic features of the invention should be reconsidered.

Claims 2-3, 8-10, 12-13, 16-17, 22-24, 26-27, 29-31, 36-39 and 42 were rejected as obvious based on the combination of Thomas and U.S. Patent 5,776,173 to Madsen et al. This rejection, and the assertions in the Office Action regarding the disclosures of the cited references, are respectfully traversed, for the following reasons.

In addition to the distinguishing features noted above, claims 2, 9-10, 16, 23-24, 29-31, and 37-39 recite a digital signal processor (DSP) for generating waveforms for electrical stimulation treatment. As disclosed in the specification, some embodiments use a DSP to shape multiple pulsatile waveforms to approximate a sine wave signal. As indicated in the specification, the use of a DSP may improve the accuracy and reliability of the generated digital signals.

The Office Action asserts that Madsen discloses a digital signal processor used in the context of an interferential therapy device. However, the passage referenced at col. 3, lines 31-34 relates to a conventional microprocessor rather than a DSP. Thus, Madsen does not disclose or suggest the use of a DSP in this context. The conventional microprocessor of Madsen is not equivalent in function to the recited DSP, nor would it produce the benefits noted in the specification. As one example, conventional microprocessors do not provide

specific functions adapted to shape and add waveforms to produce sinewave signals. Thus, those claims are not rendered obvious by the cited combination of references.

Further, like the Thomas patent, the Madsen reference does not disclose or suggest the application of interferential signals to the spinal cord and/or dorsal column areas to treat persistent pain. Therefore, the addition of Madsen to the combination does not remedy the deficiencies of Thomas in terms of suggesting this feature of the claims.

Claims 3, 12-13, 17, 26-27, recite a field-programmable gate array for generating waveforms, in addition to reciting the application of interferential signals to the spinal cord and/or dorsal column areas. Neither Thomas nor Madsen discloses or suggests a field-programmable gate array at all, and certainly not in this context. Therefore, these claims should be indicated as allowable.

With regard to the dependent claims, those claims are believed to recite independently patentable subject matter. However, those dependent claims are allowable in view of the patentability of the independent claims on which they are based. The rejections applied to the dependent claims are respectfully traversed, and for the sake of brevity, applicants will not endeavor to set forth all the reasons why particular dependent claims are patentable over the cited references.

Claims 8, 22, 36, and 42 recite using two quadripolar leads. Applicants cannot find any suggestion to use two quadripolar leads in either Thomas or Madsen. It is therefore submitted that those claims are allowable for that reason, and because they depend on allowable base claims.

Claim 4 was rejected as obvious based on the combination of Thomas and U.S. Patent 5,269,304 to Matthews. Claims 11, 14, 18, 25, 28, 32, and 40 were rejected under 35 U.S.C.

103 based on the combination of Thomas, Madsen et al., and Matthews. In general, those dependent claims recite a beat frequency in the range up to 250 Hz. Although Matthews is cited for its disclosure of beat frequencies having that same range, the combinations including Matthews do not show or suggest the features of the claims on which those claims depend, and thus do not render obvious those dependent claims.

Similarly, claims 5-7 and 19-21 were rejected under 35 U.S.C. 103 based on the combination of Thomas and U.S. Patent 5,215,086 to Terry et al. Claims 33-35 and 41 were rejected under 35 U.S.C. 103 based on the combination of Thomas, Madsen et al., and Terry et al. The Terry reference discloses a 14-volt limit and varying pulse widths. It should be noted that Terry does not disclose the specific claimed ranges, nor does the addition of the Terry reference to those combinations produce the features of the main claims. Thus, those claims are also allowable in view of the patentability of the main claims.

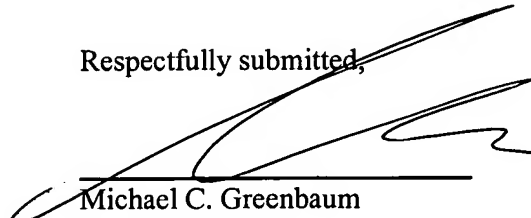
Conclusion

Applicants submit that the pending rejections are overcome by the amendments and remarks herein. Reconsideration of the rejections is requested on that basis, and a Notice of Allowance is earnestly solicited. If a telephone or personal conference would expedite prosecution, the Examiner is invited to contact the undersigned, who will cooperate appropriately to advance the case.

Please charge any deficiency in fees, or credit any overpayment thereof, to BLANK ROME LLP, Deposit Account No. 23-2185 (115747-00102). In the event that a petition for an extension of time is required to render this submission timely, Applicants hereby petition

under 37 C.F.R. § 1.136(a) for such an extension for as many months as are required to render this submission timely, and request that the PTO charge the extension fee to the deposit account as authorized above.

Respectfully submitted,



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